

Approval Date: OCT 28 2004

FREEDOM OF INFORMATION SUMMARY
SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 140-992

REVALOR-H, REVALOR-IH, and REVALOR-200
Trenbolone Acetate and Estradiol

This supplement provides for addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the indications.

Sponsored by:

Intervet, Inc.
29160 Intervet Lane
P.O. Box 318
Millsboro, DE 19966

FREEDOM OF INFORMATION SUMMARY

REVALOR-H and REVALOR-IH
Ear Implant for Heifers Fed in Confinement for Slaughter

REVALOR-200
Ear Implant for Steers and Heifers Fed in Confinement for Slaughter

1. GENERAL INFORMATION:

- a. File Number: NADA 140-992
- b. Sponsor: Intervet, Inc.
29160 Intervet Lane
P.O. Box 318
Millsboro, DE 19966
Drug Labeler Code: 057926
- c. Established Names: Trenbolone Acetate and Estradiol
- d. Propriety Names: REVALOR-H
REVALOR-IH
REVALOR-200
- e. Dosage Form: Implantation (ear implant) as per 21 CFR 522.2477

Freedom of Information Summary
NADA 140-992, Trenbolone Acetate and Estradiol
Page 2

- f. How Supplied: REVALOR-H: Each shipping container contains 4 x 1000 dose packages. Each carton contains 10 x 100 dose packages. Each box contains 10 x 10 cartridge implants. Each cartridge contains 1 implant dose. Each dose consists of 140 mg trenbolone acetate and 14 mg estradiol.
- REVALOR-IH: Each shipping container contains 4 x 1000 dose packages. Each carton contains 10 x 100 dose packages. Each box contains 10 x 10 cartridge implants. Each cartridge contains 1 implant dose. Each dose consists of 80 mg trenbolone acetate and 8 mg estradiol.
- REVALOR-200: Each shipping container contains 4 x 1000 dose packages. Each carton contains 10 x 100 dose packages. Each box contains 10 x 10 cartridge implants. Each cartridge contains 1 implant dose. Each dose consists of 200 mg trenbolone acetate and 20 mg estradiol.
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: REVALOR-H:
140 mg trenbolone acetate.
14 mg estradiol.
- REVALOR-IH:
80 mg trenbolone acetate.
8 mg estradiol.
- REVALOR-200:
200 mg trenbolone acetate.
20 mg estradiol.
- i. Route of Administration: Subcutaneous implantation on the posterior aspect of the middle one-third of the ear by means of an implant gun.
- j. Species/Class: REVALOR-H and REVALOR-IH: Heifers fed in confinement for slaughter.
- REVALOR-200: Steers and heifers fed in confinement for slaughter.

k. Recommended Dosage:

REVALOR-H: One implant containing 140 mg trenbolone acetate and 14 mg estradiol.

REVALOR-IH: One implant containing 80 mg trenbolone acetate and 8 mg estradiol.

REVALOR-200: One implant containing 200 mg trenbolone acetate and 20 mg estradiol

1. Pharmacological Category:

Steroid hormones

m. Indications:

REVALOR-H: Increases rate of weight gain and improves feed efficiency in a slow-release delivery system.

REVALOR-IH: Increases rate of weight gain in a slow-release delivery system.

REVALOR-200: This product contains trenbolone acetate and estradiol in a slow-release delivery system which increases rate of weight gain and improves feed efficiency in steers fed in confinement for slaughter.

n. Effect of Supplement:

This supplement provides for addition to the labeling of the statements “A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.” to the warning section and “Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.” immediately following the label indications.

2. DRUG EFFECTIVENESS:

No new effectiveness data are required for the approval of this supplement. The products' effectiveness has been established in the Freedom of Information (FOI) Summaries for the parent new animal drug application for REVALOR-H, REVALOR-IH, and REVALOR-200 (NADA 140992).

3. *TARGET ANIMAL SAFETY:*

No new target animal safety data are required for the approval of this supplement. The products' target animal safety has been established in the Freedom of Information (FOI)

Summaries for the parent new animal drug application for REVALOR-H, REVALOR-IH, and REVALOR-200 (NADA 140992).

4. HUMAN SAFETY:

No new human food safety data are required for the approval of this supplement. The products' human food safety has been established in the Freedom of Information (FOI) Summaries for the parent new animal drug application for REVALOR-H, REVALOR-IH, and REVALOR-200 (NADA 140992).

5. AGENCY CONCLUSIONS:

The information submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations providing for the addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the indications. The labeling is modified to conform to agency policy (69 FR 135 pages 42443-42444 dated July 15, 2004, and 69 FR 68 page 18594 dated April 8, 2004.)

The Center for Veterinary Medicine has concluded that, for these products, adequate directions for use by the layperson have been provided and the products will have over-the-counter (OTC) status. Label directions are accompanied by pictorial diagrams and detailed instruction in plain language. The drugs are not controlled substances. The products' status remains OTC. The labeling is adequate for the intended use and has sufficient warnings/statements to prevent illegal use in veal calves.

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

No patent information was submitted by the sponsor with this application.

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

REVALOR-H Package Insert
REVALOR-H Box Label
REVALOR-H Carton Label
REVALOR-H Shipping Container Label
REVALOR-IH Package Insert
REVALOR-IH Box Label
REVALOR-IH Carton Label
REVALOR-IH Shipping Container Label
REVALOR-200 Package Insert
REVALOR-200 Box Label
REVALOR-200 Carton Label
REVALOR-200 Shipping Container Label



WARNING

Not to be used in animals intended for subsequent breeding, or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

STORAGE CONDITIONS

Store in a refrigerator (2-8° C; 36-47° F) and protect from sunlight. Use before the expiration date printed on the box and on the cartridge.

PACKAGE QUANTITIES

Box of 10 x 10 cartridge implants.

Made in Austria by:
Intervet GesmbH

Distributed by:
Intervet Inc.
Millsboro, DE 19966

781000-C



NADA # 140-992, Approved by FDA

Revalor®-H

(trenbolone acetate
and estradiol)

FOR HEIFERS FED IN CONFINEMENT FOR SLAUGHTER

DESCRIPTION

Revalor®-H is an implant containing 140 mg of trenbolone acetate and 14 mg estradiol. Each implant consists of 7 small yellow pellets. Ten implants are provided in a cartridge.

Manufactured by a non-sterilizing process.

INDICATIONS

Increases rate of weight gain and improves feed efficiency in a slow-release delivery system.
Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

NOTE

Studies have demonstrated that the administration of Revalor®-H can result in decreased marbling scores when compared to non-implanted heifers.

DOSAGE

Dosage Form:

One implant containing 140 mg trenbolone acetate and 14 mg estradiol is administered to each animal. The 7 small pellets which make up the dosage of Revalor®-H are contained in one division of the multiple dose cartridge. Ten doses are in each cartridge. The cartridge is designed to be used with a special implant gun.

Route of Administration:

The implant is placed under the skin on the posterior aspect of the ear by means of a special implanter available from Intervet Inc.



With the animal suitably restrained, the skin on the outer surface of the ear should be cleaned. The implant is then administered by the method shown in the diagram below.

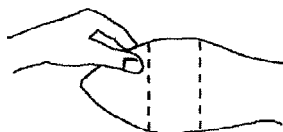


Fig. 1 - Ear of Bovine Ready for Implantation

SITE OF IMPLANTATION

After appropriately restraining the animal to allow access to the ear, cleanse the skin at the implant needle puncture site. It is subcutaneous between the skin and cartilage on the back side of the ear and below the midline of the ear. The implant must not be placed closer to the head than the edge of the cartilage ring farthest from the head. The location of insertion of the needle is a point toward the tip of the ear and at least a needle length away from the intended deposition site. Care should be taken to avoid injuring the major blood vessels or cartilage of the ear.

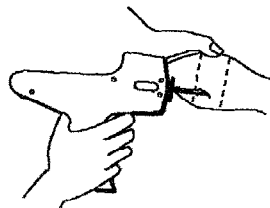
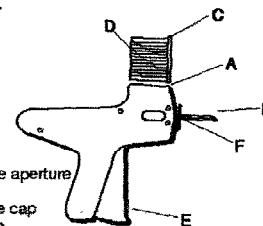


Fig. 2 - Rear View of the Bovine Ear Showing the Site for Insertion of the Implanter Needle.

METHOD OF USE

1. Do not remove the cap of the cartridge containing the implants.
2. Place the cartridge (D) with the capped end to the front into slot at the top of the implanter magazine marked (A) on the diagram.
3. Gently push the cartridge into the slot until it clicks into place.
4. The implanter is then ready for use.
5. Take the ear of the animal firmly with the free hand in the manner shown in Fig. 1. Then insert the needle into the subcutaneous tissue at the point indicated in Fig. 2.
6. After inserting the needle to its full extent, squeeze the trigger (E) gradually. Allow the pellets of the implant to be deposited in a single row.
7. Withdraw the implanter. This will advance the cartridge one groove in the magazine and the next implant is now ready for use.
8. When all the implants have been administered, the cartridge will discharge out the bottom of the magazine and may be replaced by a new one.
9. To change the needle, loosen the needle locking nut labeled (F) in Fig. 3 and replace the needle. Tighten the nut finger tight and the implanter is ready for use.



- A - Magazine aperture
- B - Needle
- C - Cartridge cap
- D - Cartridge
- E - Trigger
- F - Needle locking nut

Fig. 3 - Diagram of the Implanter and Cartridge



Manufactured by a non-sterilizing process

FOR HEIFERS FED IN CONFINEMENT FOR SLAUGHTER
Box of 10 x 10 Cartridge Implants

Revalor-H
(trehalonic acetate and estradiol)

000000 P10040
012



00021784810074

PACKAGE QUANTITIES:
Box of 10 x 10 implants
Contains 100 doses in ten cartridges with ten implants per cartridge
Each dose contains 7 small yellow pellets
Each pellet contains 20 mg of trehalonic acetate and 2 mg estradiol
STORAGE CONDITIONS:
Store in a refrigerator (2-8°C / 36-47°F) and protect from sunlight
Use before the expiration date printed on the box and on the cartridge.
INDICATIONS:
Increases rate of weight gain and improves feed efficiency in a slow-
release delivery system
Do not use in veal calves. Effectiveness and animal safety in veal calves
have not been established.
NOTE:
Studies have demonstrated that the administration of Revalor-H can
result in decreased marketing success when compared to non-implanted
heifers
485607-0

140075075
3130
L85
x-05, y-55

Revalor-H
(trehalonic acetate and estradiol)

FOR HEIFERS FED IN CONFINEMENT FOR SLA
Box of 10 x 10 Cartridge Implants

Manufactured by a non-sterilizing process

Restricted Drug (California) –
use only as directed.



Revalor-H

(trenbolone acetate and estradiol)



50021784810079

FOR HEIFERS FED IN CONFINEMENT FOR SLAUGHTER

NET CONTENTS

Box of 10 x 100 dose packages

Manufactured by a non-sterilizing process

STORAGE CONDITIONS:

Store in a refrigerator (2-8° C; 36-47° F) and protect from sunlight.
Use before the expiration date printed below and on the cartridge.

WARNING:

Not to be used in animals intended for subsequent breeding, or in dairy animals.
For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear
only. Any other location is in violation of Federal Law. Do not attempt salvage of
implanted site for human or animal food.
A withdrawal period has not been established for this product in pre-ruminating
calves. Do not use in calves to be processed for veal.

781007-C

509005 CW240 011

Intervet

Made in Austria by:
Intervet GmbH
Distributed by:
Intervet Inc.
Millsboro, DE 19966

LOT
EXP

Intervet

NADA # 140-992, Approved by FDA

Revalor[®]-H



30021784810075

(trenbolone acetate and estradiol)

FOR HEIFERS FED IN CONFINEMENT FOR SLAUGHTER

NET CONTENTS

4 x 1000 dose packages

Manufactured by a non-sterilizing process

STORAGE CONDITIONS:

Store in a refrigerator (2-8° C; 36-47° F) and protect from sunlight.
Use before the expiration date printed below and on the cartridge.

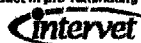
WARNING:

Not to be used in animals intended for subsequent breeding, or in dairy animals.
For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear
only. Any other location is in violation of Federal Law. Do not attempt salvage of
implanted site for human or animal food.

A withdrawal period has not been established for this product in pre-ruminating
calves. Do not use in calves to be processed for veal.

781008-C

509006 ZW240 011



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Intervet GesmbH

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Intervet Inc.
Millsboro, DE 19966

LOT
EXP



NADA # 140-992, Approved by FDA



WARNING

Not to be used in animals intended for subsequent breeding, or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

STORAGE CONDITIONS

Store in a refrigerator (2-8° C; 36-47° F) and protect from sunlight. Use before the expiration date printed on the box and on the cartridge.

PACKAGE QUANTITIES

Box of 10 x 10 cartridge implants.

Made in Austria by:
Intervet GesmbH

Distributed by:
Intervet Inc.
Millsboro, DE 19966

481420-C



Intervet

NADA # 140-992, Approved by FDA

Revalor®-IH

(trenbolone acetate
and estradiol)

FOR HEIFERS FED IN CONFINEMENT FOR SLAUGHTER

DESCRIPTION

Revalor®-IH is an implant containing 80 mg of trenbolone acetate and 8 mg estradiol. Each implant consists of 4 small yellow pellets. Ten implants are provided in a cartridge.

Manufactured by a non-sterilizing process.

INDICATIONS

Increases rate of weight gain in a slow-release delivery system.

Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

NOTE

Studies have demonstrated that the administration of Revalor®-IH can result in decreased marbling scores when compared to non-implanted heifers.

DOSAGE

Dosage Form:

One implant containing 80 mg trenbolone acetate and 8 mg estradiol is administered to each animal. The 4 pellets which make up the dosage of Revalor®-IH are contained in one division of the multiple dose cartridge. Ten doses are in each cartridge. The cartridge is designed to be used with a special implant gun.

Route of Administration:

The implant is placed under the skin on the posterior aspect of the ear by means of a special implanter available from Intervet Inc.



With the animal suitably restrained, the skin on the outer surface of the ear should be cleaned. The implant is then administered by the method shown in the diagram below.

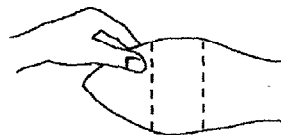


Fig. 1 - Ear of Bovine Ready for Implantation

SITE OF IMPLANTATION

After appropriately restraining the animal to allow access to the ear, cleanse the skin at the implant needle puncture site. It is subcutaneous between the skin and cartilage on the back side of the ear and below the midline of the ear. The implant must not be placed closer to the head than the edge of the cartilage ring farthest from the head. The location of insertion of the needle is a point toward the tip of the ear and at least a needle length away from the intended deposition site. Care should be taken to avoid injuring the major blood vessels or cartilage of the ear.

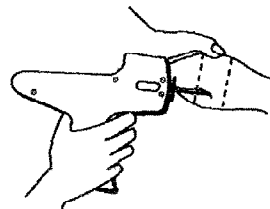


Fig. 2 - Rear View of the Bovine Ear Showing the Site for Insertion of the Implant Needle.

METHOD OF USE

1. Do not remove the cap of the cartridge containing the implants.
2. Place the cartridge (D) with the capped end to the front into slot at the top of the implanter magazine marked (A) on the diagram.
3. Gently push the cartridge into the slot until it clicks into place.
4. The implanter is then ready for use.
5. Take the ear of the animal firmly with the free hand in the manner shown in Fig. 1. Then insert the needle into the subcutaneous tissue at the point indicated in Fig. 2.
6. After inserting the needle to its full extent, squeeze the trigger (E) gradually. Allow the pellets of the implant to be deposited in a single row.
7. Withdraw the implanter. This will advance the cartridge one groove in the magazine and the next implant is now ready for use.
8. When all the implants have been administered, the cartridge will discharge out the bottom of the magazine and may be replaced by a new one.
9. To change the needle, loosen the needle locking nut labeled (F) in Fig. 3 and replace the needle. Tighten the nut finger tight and the implanter is ready for use.

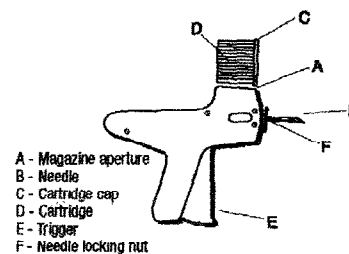
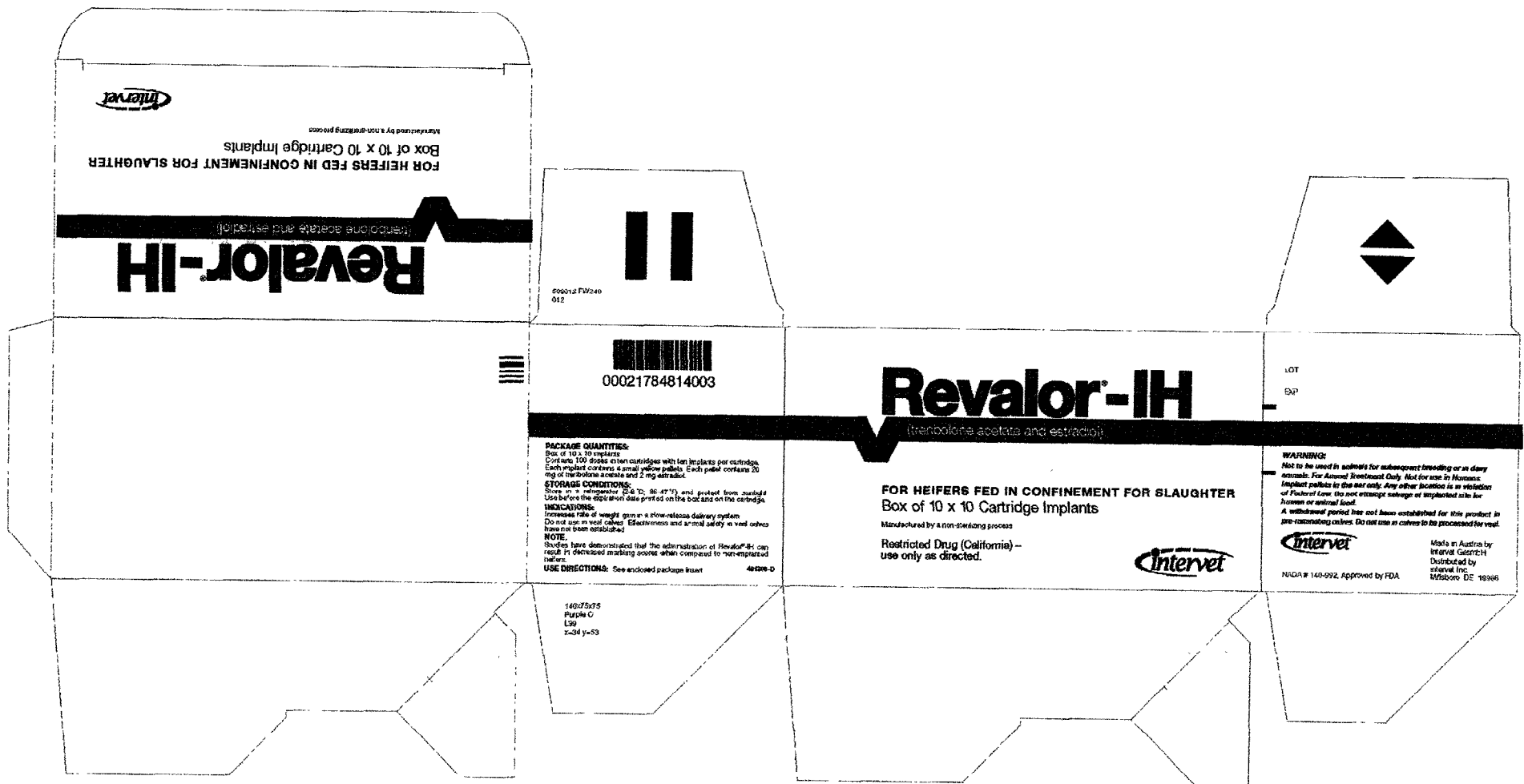


Fig. 3 - Diagram of the Implanter and Cartridge



Revalor®-IH



50021784814008

(trenbolone acetate and estradiol)

FOR HEIFERS FED IN CONFINEMENT FOR SLAUGHTER

NET CONTENTS

Box of 10 x 100 dose packages

Manufactured by a non-sterilizing process

STORAGE CONDITIONS:

Store in a refrigerator (2-8° C; 36-47° F) and protect from sunlight.
Use before the expiration date printed below and on the cartridge.

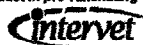
WARNING:

Not to be used in animals intended for subsequent breeding, or in dairy animals.
For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear
only. Any other location is in violation of Federal Law. Do not attempt salvage of
implanted site for human or animal food.

A withdrawal period has not been established for this product in pre-ruminating
calves. Do not use in calves to be processed for veal.

481430-C

509009 CW240 011



Made in Austria by:
Intervet GmbH
Distributed by:
Intervet Inc.
Millsboro, DE 19966

LOT
EXP



NADA # 140-992, Approved by FDA

Revalor-IH



30021784814004



N

(trenbolone acetate and estradiol)

FOR HEIFERS FED IN CONFINEMENT FOR SLAUGHTER

NET CONTENTS

4 x 1000 dose packages

Manufactured by a non-sterilizing process

STORAGE CONDITIONS:

Store in a refrigerator (2-8° C; 36-47° F) and protect from sunlight.

Use before the expiration date printed below and on the cartridge.

WARNING:

Not to be used in animals intended for subsequent breeding, or in dairy animals.

For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

781400-C

509010 ZW240 011

Intervet

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Intervet GesmbH
Distributed by:
Intervet Inc.
Millsboro, DE 19966

LOT
EXP

Intervet

NADA # 140-992, Approved by FDA



Revalor®-200

(trenbolone acetate
and estradiol)

WARNING

Not to be used in animals intended for subsequent breeding, or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

STORAGE CONDITIONS

Store in a refrigerator (2-8° C; 36-47° F) and protect from sunlight. Use before the expiration date printed on the box and on the cartridge.

PACKAGE QUANTITIES

Box of 10 x 10 cartridge implants.

Made in Austria by:
Intervet GmbH

Distributed by:
Intervet Inc.
Millsboro, DE 19966

482200-B



NADA # 140-992, Approved by FDA

509000 GW240 012

FOR STEERS AND HEIFERS FED IN CONFINEMENT FOR SLAUGHTER

DESCRIPTION

Revalor®-200 (trenbolone acetate, CAS Registry Number 10161-34-9, and estradiol, CAS Registry Number 50-28-2) is an implant containing 200 mg of trenbolone acetate and 20 mg estradiol. Each implant consists of 10 small yellow pellets. Ten implants are provided in a cartridge. Manufactured by a non-sterilizing process.

INDICATIONS FOR USE

This product contains trenbolone acetate and estradiol in a slow-release delivery system which increases rate of weight gain and improves feed efficiency in steers and heifers fed in confinement for slaughter. Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

NOTE

Revalor®-200 is not better for increased average daily gain or improved feed efficiency than Revalor®-H (140 mg trenbolone acetate/14 mg estradiol) in heifers fed in confinement for slaughter. Studies have demonstrated that the administration of Revalor®-200 can result in decreased marbling scores when compared to non-implanted steers and heifers.

DOSAGE

Dosage Form:

One implant containing 200 mg trenbolone acetate and 20 mg estradiol is administered to each animal. The 10 pellets which make up the dosage of Revalor®-200 are contained in one division of the multiple dose cartridge. Ten doses are in each cartridge. The cartridge is designed to be used with a special implant gun.

Route of Administration:

The implant is placed under the skin on the posterior aspect of the ear by means of a special implanter available from Intervet Inc.



With the animal suitably restrained, the skin on the outer surface of the ear should be cleaned. The implant is then administered by the method shown in the diagram below.

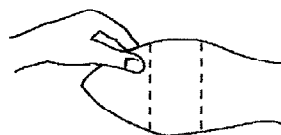


Fig. 1 - Ear of Bovine Ready for Implantation

SITE OF IMPLANTATION

After appropriately restraining the animal to allow access to the ear, cleanse the skin at the implant needle puncture site. It is subcutaneous between the skin and cartilage on the back side of the ear and below the midline of the ear. *The implant must not be placed closer to the head than the edge of the cartilage ring farthest from the head.* The location of insertion of the needle is a point toward the tip of the ear and at least a needle length away from the intended deposition site. Care should be taken to avoid injuring the major blood vessels or cartilage of the ear.

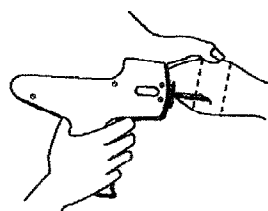


Fig. 2 - Rear View of the Bovine Ear Showing the Site for Insertion of the Implanter Needle.

METHOD OF USE

1. Do not remove the cap of the cartridge containing the implants.
2. Place the cartridge (D) (with the capped end to the front) into slot at the top of the implanter magazine (marked A on the diagram).
3. Gently push the cartridge into the slot until it clicks into place.
4. The implanter is then ready for use.
5. Take the ear of the animal firmly with the free hand (in the manner shown in Fig. 1). Then insert the needle into the subcutaneous tissue at the point indicated (in Fig. 2).
6. After inserting the needle to its full extent, squeeze the trigger (E) gradually. Allow the pellets of the implant to be deposited in a single row.
7. Withdraw the implanter. This will advance the cartridge one groove in the magazine and the next implant is now ready for use.
8. When all the implants have been administered, the cartridge will fall out of the bottom of the magazine and may be replaced by a new one.
9. To change the needle, loosen the needle locking nut (labeled F in Fig. 3) and replace the needle. Tighten the nut finger tight and the implanter is ready for use.

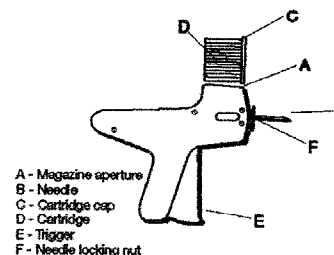


Fig. 3 - Diagram of the Implanter and Cartridge

Intervet

Box of 10 x 10 Cartridge Implants
FOR STEERS AND HEIFERS FED
IN CONFINEMENT FOR SLAUGHTER

Revalor-200
(trenbolone acetate and estradiol)

C

50097 FW245
013

V 81 2190



00021784820004

PACKAGE QUANTITIES:
Box of 10 x 10 implants
Contains 100 doses in ten cartridges with ten implants per cartridge
Each dose contains 10 small yellow pellets.
Each pellet contains 20 mg of trenbolone acetate and 2 mg estradiol.
STORAGE CONDITIONS:
Store in a refrigerator 2° to 8° C (36° to 47° F) and protect from sunlight.
Use before the expiration date printed on the box and on the cartridge.
USES:
The product is a slow-release anabolic agent containing trenbolone acetate and estradiol which increases rate of weight gain and improves feed efficiency in weaned and mature feedlot steers and heifers.
Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.
NOTE:
Revalor-200 is not better for increased average daily gain or improved feed efficiency than Revalor-MH (140 mg trenbolone acetate/14 mg estradiol) in heifers fed in confinement for slaughter.
Studies have demonstrated that the administration of Revalor-200 can result in decreased marketing scores when compared to non-implanted steers and heifers.

14027575
185 G
1.24
X=40, Y=65

Revalor-200

(trenbolone acetate and estradiol)

FOR STEERS AND HEIFERS FED
IN CONFINEMENT FOR SLAUGHTER

Box of 10 x 10 Cartridge Implants

Manufactured by a non-sterile process

Restricted Drug (California) —
use only as directed.

Intervet

LOT
EXP

USE DIRECTIONS:
See enclosed package insert.

WARNING:
Not to be used in animals for drug-resistance tracking or in dairy animals. For Animal Treatment Only. Not for use in humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted sites for human or animal food.
A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed as veal.

Intervet

NADA # 140-992 Approved by FDA

Made in Austria by
Intervet GmbH
Distributed by
Intervet Inc.
Millsboro, DE 19966

Revalor[®]-200

(trenbolone acetate and estradiol)



50021784820009

FOR STEERS AND HEIFERS FED IN CONFINEMENT FOR SLAUGHTER

NET CONTENTS

Box of 10 x 100 dose packages
Manufactured by a non-sterilizing process

STORAGE CONDITIONS:

Store in a refrigerator (2-8° C; 36-47° F) and protect from sunlight.
Use before the expiration date printed below and on the cartridge.

WARNING:

Not to be used in animals intended for subsequent breeding, or in dairy animals.
For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only.
Any other location is in violation of Federal Law. Do not attempt salvage of
implanted site for human or animal food.
A withdrawal period has not been established for this product in pre-ruminating calves.
Do not use in calves to be processed for veal.

482030-D 508998 CW240 012



Made in Austria by:
Intervet GesmbH

Distributed by:
Intervet Inc.
Millsboro, DE 19966

LOT
EXP



NADA # 140-992, Approved by FDA

Revalor®-200



30021784820005

(mestrolone acetate and estradiol)

FOR STEERS AND HEIFERS FED IN CONFINEMENT FOR SLAUGHTER

NET CONTENTS

4 x 1000 dose packages

Manufactured by a non-sterilizing process

STORAGE CONDITIONS:

Store in a refrigerator (2-8° C; 36-47° F) and protect from sunlight.
Use before the expiration date printed below and on the cartridge.

WARNING:

Not to be used in animals intended for subsequent breeding, or in dairy animals.
For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only.
Any other location is in violation of Federal Law. Do not attempt salvage of
implanted site for human or animal food.
A withdrawal period has not been established for this product in pre-ruminating calves.
Do not use in calves to be processed for veal.

782000-D

508999 ZW240 012

Intervet

Made in Austria by:
Intervet GmbH

Distributed by:
Intervet Inc.
Millsboro, DE 19966

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